Appendix II-C
Analytical Approach and Methods

The requirements in this appendix specify that the assessment process for the CRCIA is to be designed and technically conducted so as to objectively reveal probable adverse effects. Appendix II-A, in contrast, addressed the factors to be considered in the exposure process and determination of its impact. The assessment process performance needed is driven by the quality requirements for the assessment results specified in Appendix II-B. The analysis must effectively cut through the complexity of the exposure process and the consequent adverse effects to quantify the essential, or dominant, contributors to the impact. A comprehensive impact assessment can only be realized if the assessment process performs this function. Contaminants and effects are quantitatively related by modeling.

The following is an overview of the requirements in this appendix:

(C0.0-1) The assessment process shall possess the design capability to evaluate all impact, or threats of impact, listed in this document or discovered through the efforts of analysts and the CRCIA Board.

(C0.0-2) The assessment process shall identify, select, and organize the dominant sources of impact, and the dominant pathways and pathway characteristics from the sources to their adverse effects.

(C0.0-3) Models used for evaluating the exposure process and consequent impact shall be validated.

(C0.0-4) The capacity to evaluate and respond to timeliness and quality tradeoffs shall be designed into the assessment process.

(C0.0-5) The assessment process shall manage uncertainty to achieve balanced uncertainty reduction as well as integration with management of dominant factors.

(C0.0-6) The initial assessment report shall be produced within three years from project funding with whatever uncertainty can be achieved in that time period.

(C0.0-7) The architecture and integration features of the assessment process shall be specified before major funding is committed.

(C0.0-8) The assessment process shall incorporate a well-defined data quality management process.

(C0.0-9) Assessment methods that are consistent with and integrate with other impact assessment requirements shall be adopted or developed and verified.

(C0.0-10) The assessment process shall manage verification.

(C0.0-11) Analysis R&D needs shall be identified.

(C0.0-12) Standards shall be compiled especially for CRCIA as discussed in the "General Requirements" section.

C.1 Identification and Management of Dominant Factors

The requirements in this section call for the assessment to always evaluate those factors having the greatest contribution to receptor exposure and consequent impact. A comprehensive assessment must describe the dominant effects and relationships involved. By focusing on dominant factors, simplified approximations can, in most cases, be used in models without compromising their validity. However, representing behavior in terms of dominant factors is a two-edged sword. The representation problem is intractable without limiting the representation to dominant factors. But, failing to include a major contributor distorts the answer, perhaps seriously. While less important factors must be excluded to conserve resources, all important factors must be included for validity. Failure to distinguish between important and unimportant factors is not acceptable. Distinguishing between the two is the subject of this section.

Model formulation requires an iterative search for dominant process features. For example, in searching through the possible factors influencing an impact to identify the essential (dominant) set, indirect, as well as direct, effects must be considered. For example, dependencies among receptors may necessitate additional inclusions in the dominant set. A receptor of concern's dependency on other receptors may cause them to be included because effects on them are propagated to the receptor of concern. Relatively small effects on several receptors of no apparent interest may be cumulative in a receptor of interest. For example, predator/prey relationships in the food web may lead to substantial cumulative dose in a receptor of concern. If such chains of effects contribute significantly to the total impact, they must be carefully preserved in representing the progression of adverse effects. Impact may also be manifested through dynamic instabilities. For example, non-linear dynamics or positive feedback can cause sudden, unexpected population collapse in a threatened ecosystem.

Study Sets are established to define which dominant factors are to be included in the assessment. By definition, a set of dominant factors accounts for the bulk of the related impact, to any required degree of completeness. Any set of factors that fails to account for the impact to the required degree of completeness is not a dominant set. The most influential factors must be included in the dominant set, both for effective simplification and to meet completeness requirements. Dominant factors can take the form of pathways, relationships, contributors to, or elements of, dose or effects.

Conceptualization of the technical approach to the assessment shall account for, if not begin with, the selection of methods and criteria with which to select the Assessment Study Set (dominant factors) from candidate sets (all-inclusive factors) in each module of the assessment process. For any given iteration of

the assessment, all the assessment modules (see Figure C.1) shall be included. However, the depth of detail will vary; that is, the number of factors making up the Study Set from each module will differ depending on their significance to the assessment end result. The Study Set selection methods shall determine the depth of detail in each module such that a balance in significance is struck across all modules. This becomes a key in technical direction to each module's technical leader. It also becomes key in recommending budget allocations for the modules to the CRCIA management. The Study Set size and resource allocation for each module will have to be reviewed periodically as new information and modeling provide new insight to the significant contributors to the assessment final result. The Study Set selection methods are likely to involve an iterative series of sensitivity studies using first coarse, then progressively better approximations (models) of exposure and impact.

The sources of uncertainty and their extent of contribution to the overall uncertainty of the assessments end result also vary across the nine assessment modules. To conceptualize the technical approach to the assessment, methods must also be selected to estimate the extent of uncertainty contribution. Because technical effort and resources should be allocated so that overall uncertainty of results is reduced, the uncertainty from the largest contributors also must be reduced. Figure C.1 depicts this relationship graphically. Further, uncertainty and dominance are coupled. For example, some given factor may be very uncertain but of little consequence to the assessment results. Therefore, the technical approach must include methods that can estimate these combined effects and balance the depth of effort across the modules such that both the most important factors and the degree of uncertainty receive appropriate resources and investigative efforts. The requirements in this section are as follows:

(C1.0-1) A Study Set of dominant factors shall be identified for each impact that is assessed.

(C1.0-2) To achieve consistent impact fidelity, the assessment process shall construct and balance the Assessment Study Set, which shall include the following sets:

(a) Contaminants Study Set
(b) Inventories Study Set
(c) Containment Failure Scenarios Study Set
(d) Transport Paths Study Set
(e) River Entry Location Study Set
(f) River Holdup Location Study Set
(g) Critical Habitat and Uptake Location Set
(h) Selected Receptors Set
(i) Pathways Study Set
(j) Cultural Dependency Webs Study Set
(k) Exposure Mechanisms Study Set
(l) Dose Measures Study Set
(m) Dose Attributes Study Set
(n) Selected Impacts Set
(o) Limiting Scenarios Set

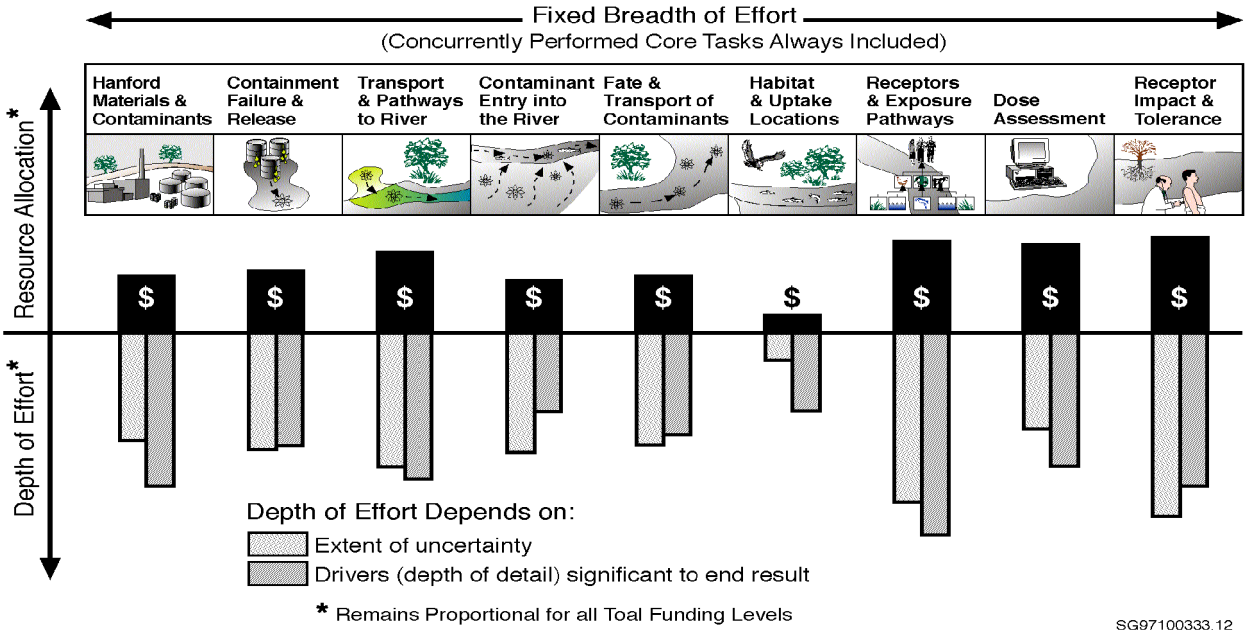

Figure C.1. Management of Dominance and Uncertainty

These sets, defined in Appendix II-B, contain the dominant entities in the exposure and harm process.

(C1.0-3) Dominant factors shall be identified progressively in an iterative elimination and review cycle with the CRCIA Board. As the dominant factors are established, the analysis team shall provide an analysis justifying each elimination for CRCIA Board review.

(C1.0-4) The importance of each eliminated factor (element of a candidate set) shall be quantified and documented by, for example, sensitivity analysis.

(C1.0-5) The iterative elimination and review cycle required in (C1.0-3) shall consider dependencies between Study Sets to preserve the validity of iterations.

(C1.0-6) Each Study Set shall be tested for completeness, according to the criteria required in Appendix B. A Study Set is complete if the explicitly represented entities belonging to it—as opposed to entities that are represented in a lump or group—contribute the required proportion of each impact.

(C1.0-7) The Study Sets derived for each individual impact shall be combined with the corresponding sets for all the other impacts to form a single Assessment Study Set valid for all the impacts to be assessed.

(C1.0-8) The degree of completeness required shall consider cost and schedule constraints. Tradeoffs of completeness against cost and schedule shall be reviewed by the CRCIA Board.

C.2 Identification and Management of Uncertainty

The requirements in this section call for identifying and quantifying uncertainties. An appropriate level of allowed uncertainty that considers both needs and costs is to be established through interaction by analysts and the CRCIA Board, as specified in Section II-C.3.1.2. The uncertainty, or probability distribution, of exposures and biological damage depends on many factors. At each step in the exposure and harm process additional uncertainties are introduced, for example, scenario uncertainties and performance uncertainties. Analysis uncertainties also are inevitably introduced in the representation of each step, also. Examples include the following:

Scenario Uncertainty:

(a) climate (recharge rate) uncertainty
(b) socio-economic evolution
(c) ecosystem evolution

Performance Uncertainty:

(a) performance of the cleanup approach causing the exposure
(b) technological uncertainty—maturity of technology and application experience
(c) institutional performance uncertainty

Analysis Uncertainty:

(a) data/parameter uncertainty
(b) model uncertainty

Uncertainty management addresses the analysis uncertainties of those assessment components that contribute the most to the uncertainties in the impacts. The available analysis resources are directed to further developing assessment components that contribute the most and that can be brought into consistency with the smaller uncertainty contributors for the least commitment of resources. An iterative approach, starting from a coarse initial analysis and progressing through successively more refined analyses, with uncertainty management at each step, is being used. Irreducible uncertainty is reached when further developing the assessment components that are the largest sources of uncertainty is beyond the available time and resources.

Note that dominance among uncertainties is closely related to dominance as discussed in the previous section. Both shall be managed in a unified process. For example, the methods in National Council on Radiation Protection and Measurements (NCRP) Commentary No. 14 (1996) might be adapted. The following is an overview of the requirements in this section:

(C2.0-1) The level of uncertainty achieved in intermediate and final comprehensive impact assessment results for all assessment end points shall be quantified.

(C2.0-2) The uncertainty of any given impact shall be managed under planned funding and schedule, to achieve acceptable contributions from those components that contribute the most to the uncertainty of the given impact. This is to be accomplished by managing the development of the impact assessment components that contribute the most to that uncertainty.

(C2.0-3) The rationale and basis for the assessment of predicted impact uncertainties shall be communicated to the stakeholders and the public during the planning stages of the impact assessment by the CRCIA Board in cooperation with the analysts.

C.2.1 Control of Analysis Uncertainty

The requirements in this section call for controlling analysis uncertainty. The relative contribution of each source of uncertainty to the uncertainty in impact shall be established to effectively allocate the uncertainty allowable for each assessment component. Project resources are to be allocated to improving the representation of assessment components that are the major contributors to overall uncertainty. The acceptable level of uncertainty depends on the margin between expected impact levels and the maximum acceptable levels of impact. The requirements in this section are as follows:

(C2.1-1) Analysis uncertainty shall be planned so that a margin exists between impact upper bounds predicted with confidence and maximum acceptable level of impact, if feasible. Unfeasibility shall be communicated to cognizant cleanup management, stakeholders, and the public.

(C2.1-2) Opportunities for refining assessment components that are primary contributors to impact uncertainty shall be identified.

(C2.1-3) The relationship between impact assessment cost and assessment uncertainty level shall be established for each impact evaluated.

(C2.1-4) Analysis uncertainties shall be allocated among assessment components in accordance with their contribution to one or more impacts.

(C2.1-5) Resources shall be allocated among assessment components based on the analysis uncertainty contributions of each component. (See Section II-C.3.1.2 and Appendix II-D.)

(C2.1-6) The CRCIA Board shall be consulted about the acceptable level of uncertainty in predicted impacts for each impact assessment endpoint.

(C2.1-7) The predicted impacts, uncertainties, interpretations, and implications shall be communicated to the public and stakeholders by the CRCIA Board in cooperation with the analysts.

C.2.2 Stochastic Characterization of Exposure and Harmful Effects

The requirements in this section call for evaluating the probabilistic aspects of exposure and impact process behavior, as well as the uncertainties in the representations used in the impact assessment. Impact uncertainty representation supports uncertainty management and interpretation of assessment results. The requirements in this section are as follows:

(C2.2-1) An initial estimate of exposure and impact process uncertainties shall be provided during the early planning phase of the assessment.

(C2.2-2) Further refinement and quantification of the initial uncertainty estimate shall be provided early in the assessment process.

(C2.2-3) Tool uncertainty capabilities shall be monitored during tool development and data acquisition.

(C2.2-4) Uncertainty assessment shall be provided in assessment results.

C.2.2.1 Identification of Uncertainty Sources

The requirements in this section call for identifying all types of uncertainty sources. The requirements in this section are as follows:

(C2.2.1-1) The impact assessment process shall identify, validate, and organize uncertainties, their sources, and characteristics.

(C2.2.1-2) Dominant sources of uncertainty shall be identified.

(C2.2.1-3) Model components, model parameters, and data that contribute the most uncertainty to predicted impacts shall be identified by sensitivity analyses of impact assessment predictions.

C.2.2.2 Characterization of Probabilistic Exposure and Harmful Effects Process Behavior

The requirements in this section call for characterizing the inherent uncertainties in the exposure and harm process. Many of the harmful effects of exposure can only be related to dose in terms of harm frequency in a population, not as certain outcomes in any particular individual. Furthermore, many hazards are in the future, which is inherently uncertain, and can only be characterized by likely parameter ranges. The workings of the exposure and harm process shall be evaluated over the range of likely outcomes to evaluate the robustness of any cleanup solution. The requirements in this section are as follows:

(C2.2.2-1) The inherent probabilistic behavior of exposure and harmful effects process steps shall be characterized. Some examples are as follows:

- uncertainties in contact between receptors and contaminants (resources) including consideration of *spatial* uncertainties
- scenario uncertainties

(C2.2.2-2) Statistical characteristics of (probabilistic) impacts shall be characterized.

(C2.2.2-3) Statistical characteristics of the exposure process shall be characterized over individuals in selected sub-populations.

(C2.2.2-4) The statistical characterizations (distributions) of dose and impacts shall represent the exposure of the most exposed fraction of the selected sub-populations to the satisfaction of the CRCIA Board.

C.2.2.3 Characterization of Analysis Uncertainty

The requirements in this section call for characterizing the uncertainties in the exposure and harm process representations used in the impact assessment. The exposure and harm process is represented by models and the parameters used in the models. Data and information on the exposure and harm process support quantification of relationships among the parameters and models throughout the exposure and harm process. The requirements in this section are as follows:

(C2.2.3-1) Uncertainties in the representation of the exposure and harmful effects process steps shall be characterized.

(C2.2.3-2) The degree of uncertainty in the predicted impact severity for each assessment end point shall be described by a distribution (histogram) of impact severity obtained.

(C2.2.3-3) The exposure and harmful effects process representation shall be evaluated for uncertainty in total dose or total impact using computer simulations. Therefore, the uncertainty of process features that determine total dose or impact, such as peak concentration and peak duration, shall be evaluated. Timing is only of interest to the extent that it affects total impact; for example, the effect of timing on radioactive decay, which in turn reduces peak radionuclide concentration at the River. Where timing of the peak has a small effect on total dose, such as in the case of nuclides with half-lives that are much longer than the travel time of the peak, its uncertainty is of secondary interest.

C.2.2.3.1 Quantification of Parameter Uncertainty. The requirements in this section call for quantifying uncertainties introduced from uncertainties in exposure and harm process parameters. The requirements in this section are as follows:

(C2.2.3.1-1) The distributions of uncertain parameters in the exposure and harm process shall be estimated and considered in evaluating the uncertainty in each impact.

(C2.2.3.1-2) The operation of parameter uncertainty over time (stochastic processes) shall be evaluated and represented to the extent justified by its effect on impact uncertainty.

C.2.2.3.2 Quantification of Model Uncertainty. The requirements in this section call for quantifying uncertainties introduced as a result of uncertainties in exposure and harm process models. The requirements in this section are as follows:

(C2.2.3.2-1) Model uncertainty shall be evaluated and considered in overall impact analysis uncertainty.

(C2.2.3.2-2) Model uncertainty evaluation shall be integrated with the iterative model refinement process used in going from candidate sets of entities to the final Study Set. (See Section II-C.1.)

C.3 Analytical Architecture and Integration

The requirements in this section call for establishing the assessment process architecture as a basis for planning or scheduling. The necessary assessment functions and their interfaces shall be identified and specified. An assessment architecture shall do the following:

- support iterative refinement of analysis products
- use resources effectively by performing up-front scoping analyses to ensure purposeful and efficient execution of main-line tasks
- proceed along a well-defined path to the final product
- be well integrated as demonstrated by the use of pre-defined and pre-planned intermediate analytical products to effectively enable the later assessment project functions that depend on them

The following is an overview of the requirements in this section:

(C3.0-1) Assessment process functions shall be identified and specified.

(C3.0-2) An explicit study architecture with associated internal and external interfaces shall be specified.

(C3.0-3) Assessment intermediate and final products shall be specified in the study design.

C.3.1 Functional Definition of the Assessment Process

The requirements in this section call for completing a complete functional definition of the assessment process prior to assessment planning. They also call for identifying the functions needed to produce the products identified in Section II-C.3.2. The requirements in this section are as follows:

(C3.1-1) Functions that define Management, Planning, and Control shall be specified.

(C3.1-2) Functions that define Technical Development and Integration shall be specified.

(C3.1-3) Functions that define Assessment Tool Development shall be specified.

(C3.1-4) Functions that define Assessment Results Production shall be specified.

C.3.1.1 Management, Planning, and Control Functions

The requirements in this section call for defining Management, Planning, and Control functions. Management, Planning, and Control functions receive direction from, and provide information to, entities external to the project. They provide internal project direction and control, coordination, resources, and processes necessary to provide periodic assessment reports, which correspond to changes in the Hanford Disposal Baseline.

Assessment project management includes 1) setting assessment project goals and objectives; 2) establishing organizational structures and interfaces; 3) establishing processes for performing activities; 4) planning, allocating resources, and providing direction; and 5) monitoring and controlling performance of project activities to achieve those goals and objectives. The requirements in this section are as follows:

(C3.1.1-1) The functionality or functional roles identified or implied in Appendix D shall be reflected in the functions identified under Management, Planning, and Control. Management, Planning, and Control functions shall conform to the principles outlined in Appendix D.

(C3.1.1-2) Management, Planning, and Control shall provide the functional interfaces specified in Appendix D.

(C3.1.1-3) Management, Planning, and Control shall conduct external interactions and shall receive and transmit all information between the project and appropriate external entities. External entities include the following: 1) state governments, 2) federal government, 3) Indian Nations, 4) citizens of the region, and 5) affected peoples and cultural groups within the regional population. It shall provide input and feedback to CRCIA requirements.

(C3.1.1-4) Management, Planning, and Control shall provide strategic and contingency planning for high-level strategic assessment options and contingency plans. It shall develop strategies for collaborating with Hanford projects and incorporating assessment results into the Hanford decision process.

(C3.1.1-5) Management, Planning, and Control shall provide contract business management to develop and administer contracts for services, equipment, and materials.

(C3.1.1-6) Management, Planning, and Control shall perform administrative services to provide personnel, training, physical facilities, communications services, and other administrative support to the project.

(C3.1.1-7) Management, Planning, and Control shall control the assessment project by organizing, planning, monitoring, directing, and managing changes to work scope, schedule, cost, and technical baselines, as well as to standard practices.

(C3.1.1-8) Management, Planning, and Control shall provide quality assurance. It shall ensure that each assessment project element has its own quality assurance process in place and that all processes and services are performed according to the intent of accepted standard practices.

C.3.1.2 Technical Development and Integration Functions

The requirements in this section call for defining Technical Development and Integration (TDI) functions. TDI functions translate the project mission and constraints into a complete, integrated set of exposure and harm process functions, allocated requirements, and interfaces for the CRCIA description. They establish and direct the technical definition of the assessment throughout the project development and production phases, leading to acceptance of the resulting assessment by assessment users and affected peoples. They also control tool performance capability and data quality.

TDI functions identify technical quality measures and acceptance criteria for the assessment. TDI functions also provide integration of assessment technical information and technical development activities through review, evaluation, and approval of the evolving assessment technical description and associated data. TDI functions allocate allowable uncertainty and recommend resource allocation to each assessment element and provide technical direction of assessment production.

Activities that implement TDI functions are performed throughout all assessment project phases up to acceptance of the assessment by Hanford stakeholders and other assessment users. Early in the project, mission and functional analyses are performed to identify the exposure and harm process functions that must be described both to fulfill the project mission requirements and to allocate CRCIA requirements to the functions. These allocated requirements are translated from assessment technical, description, and production (including schedule) needs, as well as regulatory or other needs and constraints. User requirements are also defined for the assessment results and assessment description fidelity and uncertainty. This initial assessment functional structure is verified within TDI and provided as required functionality to the Develop Assessment Tools and Produce Assessment Results functions. These verified requirements and allocations constitute the initial functional requirements baseline for the CRCIA that is controlled by TDI.

The CRCIA project cycle evolves from exposure and harm process definition, to development, and finally to assessment production. TDI continues to evaluate, assess, disseminate, and catalog information received from other project functions to ensure that the assessment functional structure is maintained, that all project functions are provided with a consistent set of controlled technical information, and that the assessment elements and lower-tier models are designed and data acquired in accordance with the verified requirements and are implemented and tested in accordance with approved designs and test requirements. Recommended resource allocations to assessment elements are provided by TDI to Management, Planning, and Control. TDI has approval authority for the completeness of candidate sets and Study Sets. Requests for review/reassessment of CRCIA requirements are processed by TDI to provide, in conjunction with the Control Assessment Project function, change control for the assessment project.

TDI provides the current status of the controlled assessment description, including technical baseline information, to all other assessment functions. TDI provides a centralized integration and control source for assessment technical information (assessment description) to ensure that all project functions are using a common, approved information set. The requirements in this section are as follows:

(C3.1.2-1) TDI functions shall control the assessment technical features such that the dominance and uncertainty requirements in Sections II-C.1 and II-C.2 are satisfied.

(C3.1.2-2) TDI functions shall integrate representation of the exposure and harm process to ensure that the primary elements of harm are captured with minimum uncertainty for the resource and schedule constraints imposed.

(C3.1.2-3) TDI functions shall establish the CRCIA requirements.

(C3.1.2-4) TDI functions shall define the exposure and harm process structure (functionality and interfaces).

(C3.1.2-5) TDI functions shall provide the definition of needed research (R&D).

(C3.1.2-6) TDI functions shall select river scenarios and identify disposal plans.

C.3.1.3 Assessment Tool Development Functions

The requirements in this section call for defining Assessment Tool Development functions. The Assessment Tool Development functions develop all computation tools and data (for example, ecosystem information, biological effects parameters) needed to assess impacts on the river over the full range of river scenarios required, as well as over the anticipated Hanford Disposal Baseline. They also provide all needed statistical definition and calculation tools. The requirements in this section are as follows:

(C3.1.3-1) The Assessment Tool Development functions shall represent the exposure and harm process.

(C3.1.3-2) The Assessment Tool Development functions shall mechanize the representation of the exposure and harm process.

(C3.1.3-3) The Assessment Tool Development functions shall perform stochastic characterization of the exposure and harm process.

(C3.1.3-4) The Assessment Tool Development functions shall identify and evaluate available information and previously developed tools for use in CRCIA.

C.3.1.4 Production of Assessment Results Functions

The requirements in this section call for defining Production of Assessment Results functions. The Production of Assessment Results functions provide a verified, published report of river impact assessment results for all required river scenarios and the current Hanford Disposal Baseline. The requirements in this section are as follows:

(C3.1.4-1) The Production of Assessment Results functions shall publish each final assessment report.

(C3.1.4-2) The Production of Assessment Results functions shall publish each draft assessment report.

(C3.1.4-3) The Production of Assessment Results functions shall verify and validate the results for each assessment report.

(C3.1.4-4) The Production of Assessment Results functions shall evaluate impacts to ecosystems, humans, and cultures.

(C3.1.4-5) The Production of Assessment Results functions shall prepare input data for evaluating impacts to ecosystems, humans, and cultures.

C.3.2 Assessment Process Interfaces

The requirement in this section calls for defining the input information categories, intermediate assessment products, and final assessment products during design of the assessment process. The requirement in this section is as follows:

(C3.2-1) All the information and assessment tool interfaces necessary for satisfactory assessments shall be defined and specified during the early planning stage of the project.

C.3.2.1 External Assessment Process Interfaces

The requirements in this section call for defining external interfaces early in the project. The external assessment process interfaces are the assessment reports and other information produced by the project for

external consumption, as well as the information that outside sources provide to the project. Other external interfaces relate to providing funding and other resources to the project. The requirements in this section are as follows:

(C3.2.1-1) The following external interfaces of the assessment process shall be included among those defined and specified:

(a) Assessment Report: The collected characterization of Hanford impacts on the Columbia River. It is a revised version of the Draft Assessment Report, reflecting input from peer reviewers and the public. For assessment report presentation requirements, see Section II-B.4, "Assessment Reporting."

(b) Draft Assessment Report: Initial version of the Assessment Report, prior to peer review, public comment, and revision.

(c) Resources: Congressional appropriations and scientific and technical resources.

(d) Resource and Time Constraints: Constraints on the assessment period, budget, and personnel.

(e) Legal and Policy Drivers: Regulatory and policy considerations.

(f) Information Utilization Requirements: Decision makers' information requirements. Definition of usable information. Information needs of all parties to any decisions, including all stakeholders.

(g) Stakeholder Needs: Stakeholder needs for information to participate effectively in cleanup decisions.

(h) Hanford Disposal Information: All information on DOE's Richland Operations Office commitments to explicit waste disposal end-states at Hanford. This information can take the form of a waste disposal baseline for the entire Hanford inventory, specific waste disposal plans in the multi-year work plan, budgeting assumptions, or other indications of DOE's intentions for disposal of current and future waste inventories.

(i) Existing Hanford Information: Existing Hanford information available from all sources.

(j) Existing Assessment Tools: Assessment tools produced outside CRCIA that could potentially be applied within CRCIA, if they are shown to meet CRCIA requirements.

C.3.2.2 Internal Assessment Process Interfaces

The requirements in this section call for defining internal interfaces early in the project. The internal assessment process interfaces are the intermediate information and assessment tools produced by individual assessment functions that enable other assessment functions. The requirements in this section are as follows:

(C3.2.2-1) All the internal information and assessment tool interfaces necessary for satisfactory assessments shall be defined and specified during the early planning stage of the project. These are the basis for intermediate deliverables or milestones.

(C3.2.2-2) The following internal interfaces of the assessment process shall be included among those defined and specified:

(a) Stakeholder Requirements: Information obtained from external entities that express needs and concerns. This information is obtained incrementally over time; however, it is concentrated early in the project to stabilize the project definition.

(b) Project Direction: Project direction consists of work plans, schedule, budget, authorized work, and dispositioned changes. Project direction is periodic, including document revisions and a continuing stream of changes.

(c) CRCIA Requirements: The most recent version of the CRCIA requirements approved by the CRCIA Board. Requirements are established and driven to convergence early in the project to stabilize the project definition and approach.

(d) Assessment Architecture: Specifies individual technical approaches, methods, acceptable representations, input data, output deliverables, and the definition of required data/information deliverables among individual assessment elements (interfaces between representation elements). The interfaces between representation elements define the model interfaces. Assessment Architecture provides the functional definition of assessment process. Specifications are implemented as timely directives to assessment element tasks. Assessment architecture is established and driven to convergence early in the project to stabilize the project definition.

(e) Recommended Resource Allocation: Recommended resource allocation between assessment elements, based on control of impact uncertainties. Recommendations are revised periodically to coincide with assessment iterations.

(f) Tool Scope: On-going control of tool capability and data quality for individual assessment elements. The class of tool and data requirements imposed to ensure that developed tools possess adequate performance capability to satisfy the uncertainty

allocations eventually to be assigned when the tool is used in the "produce assessment results" phase. Also, that the quality of data used in tool relationships or input is consistent with required uncertainty allocations. Tool scope includes capacity requirements in each tool for the sets it uses from the Assessment Study Set, as well as the river scenarios and disposal methods required, and all scenario variables required. Tool Scope is revised periodically to coincide with assessment iterations.

(g) Uncertainty Allocation: Ongoing fidelity direction to individual assessment elements. Uncertainty limits prescribed for each step in the harm process representation used in producing assessment results. Allocations are revised periodically to coincide with assessment iterations.

(h) Product Deviations: The estimated uncertainties and requirements deviations contained in assessment results. Deviations are revised periodically to coincide with assessment iterations.

(i) Assessment Tools: Includes simulation models, statistical definition, statistical tools, and new data. Assessment tool development/use is iterative.

(j) Study Sets: Composed of the collection of Study Sets for all collections of entities to be included in the study, such as contaminants, inventories, receptors, impacts, and pathways. Iterative Study Set versions are defined to converge to the final assessment Study Set.

(k) Fidelity: The estimated performance capabilities of tools under development. Minimum representation and implementation uncertainties estimated at each stage of tool development for all steps in the harm process from tools operated at maximum set sizes, web complexities, with all available data, etc. Adequacy of each Study Set (subset of the Assessment Study Set). Analysis uncertainty resulting from data uncertainty is part of fidelity definition. The initial estimate of fidelity is based on tool scope and size/uncertainty tradeoff estimates that are provided as input to determining tool scope. Fidelity includes estimates of sensitivity to included parameters. Fidelity monitors the iterative evolution of tools.

(l) R&D Results: Study results that enable improved assessment methods or tools.

(m) R&D Workscope: Scope of work definition for R&D needed to permit conformity to CRCIA requirements. Includes definition of R&D work, R&D results needed, time when results are needed, consequences of not having the R&D results, and estimated time to do R&D work. R&D work scope is established early in the project and changed more and more infrequently during the project.

C.4 Data Quality

The requirements in this section call for controlling data quality, data gaps, data acquisition, and verification and validation in a way that is balanced and consistent with other requirements. In particular, data quality shall be consistent with the representation of the exposure and harm process. Data quality objectives are identified in the Technical Development and Integration assessment function and satisfied in the Assessment Tool Development function. Data quality plays a fundamental role in assessment quality; however, data quality shall be controlled so that the quality and completeness attributes of the data contribute to overall assessment quality. An overview of the requirements in this section is as follows:

(C4.0-1) Data quality shall be controlled so that it is integrated and consistent with overall representation fidelity requirements.

(C4.0-2) Data and information inadequacies shall be rectified to the extent possible for those uncertainty sources that are the greatest contributors to the uncertainty of the predicted impacts.

C.4.1 Identification of Data Gaps

The requirements in this section call for managing data gaps in a way that is balanced and consistent with other requirements. Data gaps are particular classes of unavailable data that affect the uncertainty of the assessed impacts. The requirements in this section are as follows:

(C4.1-1) Candidate additional data needed to support parameters and relationships shall be identified, and their relation to impact uncertainty shall be established.

(C4.1-2) The type, quality, and quantity of data and information needed to meet impact assessment uncertainty requirements shall be determined by the following:

(a) applying the Data Quality Objectives process

(b) conducting preliminary computer simulation (Monte Carlo) uncertainty and sensitivity analysis on the impact models

(c) applying the applicable regulatory requirements

(C4.1-3) Risk assessment conclusions shall be drawn only from supporting data whose quality and quantity are consistent with the design level of uncertainty. This means that conclusions shall only be drawn if supporting data are available.

(C4.1-4) Limits on treatment of missing data shall be established by analysts in consultation with the CRCIA Board, for example, the fraction of (biologically significant) non-detect concentration data in the environment that is allowable for acceptable application of Winsorization.

C.4.2 Data Verification and Validation

The requirements in this section call for managing data verification and validation in a way that is balanced and consistent with other requirements. The requirements in this section are as follows:

(C4.2-1) An assessment process function shall be established to verify and validate data quality.

(C4.2.-2) The Data Quality Assessment process (EPA 1994) shall be used to evaluate if currently available data and information are adequate to meet the established Data Quality Objectives.

C.4.3 Data Acquisition

The requirements in this section call for managing data acquisition in a way that is balanced and consistent with the representation approach. The requirements in this section are as follows:

(C4.3-1) Decisions on data acquisition shall be integrated with the overall treatment of dominance and uncertainty. (See Section II-C.2 and II-C.3.)

(C4.3-2) Exposure, contaminant uptake, and transfer information shall be collected so that the data can be used in Hanford ecological risk models.

(C4.3-3) Study results shall be documented and the information obtained shall be made generally available in a database.

C.4.4 Control of Data Quality

The requirements in this section call for controlling data quality during the assessment process to balance data completeness and quality with the representation approach. The requirements in this section are as follows:

(C4.4-1) An assessment process function shall be established to control data quality in relation to required assessment fidelity and the exposure and harm process representation used.

(C4.4-2) Data acquisition plans shall be reviewed by the CRCIA Board.

C.5 Assessment Methods

The requirements in this section describe the characteristics that the analysis methods and procedures used in the assessment shall have. The requirements in this section are as follows:

(C5.0-1) Assessment methods shall estimate the likelihood and severity of all the impacts to be assessed.

(C5.0-2) The assessment methods used shall satisfy required interfaces between assessment elements.

(C5.0-3) Assessment methods shall satisfy the quality requirements in Appendix II-B.

(C5.0-4) Risk assessment methods shall be able to detect any impact level that affects the sustainability, robustness, and viability of the Columbia River ecosystem or stakeholder cultures.

C.6 Verification and Validation

The requirements in this section call for properly verifying and validating the assessment process design before it is implemented. The requirements in this section are as follows:

(C6.0-1) Biological impact results shall be verified and validated.

(C6.0-2) Assessment elements shall be verified and validated.

(C6.0-3) Interfaces between assessment elements (assessment tools) shall be verified and validated.

(C6.0-4) Acceptable impact uncertainty levels for validating the models used shall be determined in consultation with the CRCIA Board and subject to its approval.

(C6.0-5) Traceability of correlation parameters shall be established, maintained current, and documented.

C.7 Analysis Research and Development Needs

The requirements in this section call for promptly identifying R&D needs for new or modified analytical methods. R&D shall be used to satisfy CRCIA requirements. They also call for R&D expenditures and efforts to focus on areas that make the greatest contribution to reducing impact uncertainty or to improving assessment process performance.

Research to determine relative importance of factors that influence adverse effects shall be an important part of identifying dominant assessment factors. The benefits of such research include

assessment completeness and uncertainty reduction. Because of the delays and expense such development efforts entail, every effort is expected to be made to incorporate the requirements for this assessment into previously planned and scheduled research efforts. An overview of the requirements in this section is as follows:

(C7.0-1) The R&D needs implied by CRCIA requirements shall be identified in the early planning stage of the project. The time that R&D results are needed to support the project schedule, as well as feasible time to perform the research, shall be estimated.

(C7.0-2) The necessary R&D workscope shall be integrated across assessment elements, balancing uncertainty and dominance with cost at the overall assessment level. R&D work scope shall be identified and integrated within assessment elements and provided to Technical Development and Integration to maximize efficiency across the assessment. Compromise within assessment elements may be desired for the overall good of the assessment because of uncertainty and dominance considerations.

(C7.0-3) The R&D identification process shall review past efforts and planned projects for applicability to the CRCIA effort.

(C7.0-4) Proposed R&D projects shall be prioritized, based on how the results affect the quality of the impact assessment. An example of an R&D project result is the level of uncertainty in an assessment element.

(C7.0-5) R&D needs identified in the Columbia River screening assessment shall be evaluated.

(C7.0-6) R&D needed to validate dose/impact correlations shall be identified and included in overall R&D work scope.

(C7.0-7) R&D needs shall be brought before the CRCIA Board.

C.7.1 Contaminant Transport Research and Development

The requirements in this section call for identifying contaminant transport R&D needs. The requirements in this section are as follows:

(C7.1-1) R&D needs associated with the model of site-wide groundwater transport shall be identified. Transport of water and soluble contaminants in the vadose zone is a primary aspect of these needs.

(C7.1-2) R&D on parameters for a site-wide groundwater model shall be conducted.

(C7.1-3) Site-wide groundwater transport modeling R&D shall be subject to approval by the CRCIA Board.

C.7.2 Exposure and Dose Research and Development

The requirements in this section call for identifying exposure and dose evaluation R&D needs. The requirements in this section are as follows:

(C7.2-1) R&D needs associated with receptor contact with and uptake of contaminants shall be identified.

(C7.2-2) R&D needs associated with dose measurement for particular receptors and impacts shall be identified.

C.7.3 Impacts Research and Development

The requirements in this section call for identifying impact evaluation R&D needs. The requirements in this section are as follows:

(C7.3-1) R&D needs associated with impacts to be assessed shall be identified.

(C7.3-2) R&D needs associated with ecosystem sustainability shall be identified.

(C7.3-3) R&D needs associated with cultural quality of life shall be identified.

(C7.3-4) R&D needs associated with the viability of socio- and eco-entities shall be identified.

(C7.3-5) Basic toxicological R&D on biota shall be performed, including but not limited to the following:

(a) effects of metals on invertebrates
(b) effects of Trichloroethylene and its breakdown products on salmon

(C7.3-6) Impacts to Native Americans and others and their relationship to contaminant concentrations shall be investigated. R&D on assessment methods for Native American impacts shall be undertaken.

C.8 CRCIA Standards, Regulations, and Guidelines

The requirements in this section identify the standards to be used in the analytical process (see also “Standards” in the section “Principles and General Requirements.”)

(C8.0-1) The applicability of federal, State of Washington, and State of Oregon laws and guidelines for analyses shall be evaluated and reported to the CRCIA Board.

(C8.0-2) Analysis methods shall be compatible with and capable of providing information pertinent to State of Washington and Oregon water regulations. Regulations such as Washington's Clean Water Act, Surface Drinking Water Act, and Model Toxins Control Act shall be evaluated for applicability and relevance. The evaluation shall be subject to approval by the CRCIA Board.

(C8.0-3) The most stringent applicable standards shall be identified and applied to establishing technical analysis performance requirements. For example, salmon related standards shall be applied in regions where salmon are affected. This means an analytical sensitivity below 11 parts per billion of chromium (the concentration at which injury to juvenile salmon occurs) in salmon redds shall be achieved rather than 50 parts per billion as required by the clean water (human) standard.

C.9 Reference

U.S. Environmental Protection Agency. 1994. *Guidance for the Data Quality Objectives Process*. EPA QA/G-4, Washington, D.C.